

December 5, 199D

Hair Science Society of Japan

Report on the Result of Patch Test

1. Purpose of test:

Concerning a cosmetic product supplied by Nikko Chemicals K.K. with a request of test, this patch test was carried out for the purpose of examination of its influence (safety) on the skin of healthy and normal persons.

2. Sample:

BELESA SKIN CREAM UT, Lot. No. 901116, of a formulation as follows:

Standard	Ingredient	Weight %
JSCI	1. Self-emulsifiable glyceryl monostearate	4.00
"	2. Polyethyleneglycol monostearate (40 E.O.)	2.00
"	3. Squalane	15.00
Attach. 1	4. Glyceryl tri-octanoate	15.00
JSCI	5. Behenyl alcohol	3.00
"	6. Batyl alcohol	2.00
Attach. 2	7. UVINUL T 150	3.00
JSCI	8. 1,3-butylene glycol	3.00
"	9. p-hydroxybenzoate ester	0.15
"	10. Purified water	Proper dose
Total		100.00

3. Test method:

(1) Persons tested: 20 males and 21 females, aged between 20 and 53.

(2) Patch test:

By using Fin Chamber (EPITEST product imported/marketed by Taisho Pharmaceutical; Lot No. 0209S), a test pad was applied on the flexor side of the upper arm for 48 hours and then was carried out evaluation.

Namely, the test pad was removed after application and evaluation was made by observing the state of the skin 30 minutes after the removal ("evaluation time 48 hours" in the Attached Table) and 24 hours after the removal ("evaluation time 72 hours" in the Attached Table).

(3) Evaluation of skin reaction:

Negative: - : No reaction all

± : Slight erythema

Positive: + : Apparent erythema

++ : Erythema and swelling; erythema and papule

+++ : Vesicula additionally

This patch test was carried out and evaluated by Dr. K. Nagashima, Director of the Hair Science Society of Japan and head of the Dermatology Dept. of the JR Tokyo Central Hospital.

4. Test result:

The result of the patch tests on 41 persons is shown in the Attached Table. The reaction of the skin at 30 minutes after removal of the test pad ("Evaluation time 48 hours" in the Attached Table) and at 24 hours after removal of the test pad ("Evaluation time 72 hours" in the Attached Table) was evaluated as (-) for all persons tested.

Also on the 7th day after removal of the pad, the evaluation was (-) without exception. No abnormalities were observed at all.

5. Conclusion:

Upon request from Nikko Chemicals K.K., a patch test was carried out to examine the influence (safety) of a cosmetic product applied onto healthy and normal human skin. All reactions obtained were negative. It may be considered, therefore, that BELESA SKIN CREAM UT (Lot No. 901116) tested is little probable to cause continuous dermal irritation and has a high safety.

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M. Komuro

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Translator

The result of patch test (1)

No.	Test Person	Sex	Age	Time	Result	Condition of test person
1	S.A.	♂	53	48 hrs. 72 hrs.	- -	Healthy
2	E.I.	♀	28	48 hrs. 72 hrs.	- -	Healthy
3	K.I.	♀	50	48 hrs. 72 hrs.	- -	Healthy
4	S.I.	♀	27	48 hrs. 72 hrs.	- -	Healthy
5	A.K.	♂	37	48 hrs. 72 hrs.	- -	Healthy
6	Y.K.	♂	53	48 hrs. 72 hrs.	- -	Healthy
7	A.K.	♀	32	48 hrs. 72 hrs.	- -	Healthy
8	I.S.	♂	26	48 hrs. 72 hrs.	- -	Healthy
9	H.D.	♂	30	48 hrs. 72 hrs.	- -	Healthy
10	J.T.	♀	28	48 hrs. 72 hrs.	- -	Healthy
11	H.T.	♂	54	48 hrs. 72 hrs.	- -	Healthy
12	T.N.	♂	28	48 hrs. 72 hrs.	- -	Healthy
13	K.M.	♀	39	48 hrs. 72 hrs.	- -	Healthy
14	T.M.	♂	27	48 hrs. 72 hrs.	- -	Healthy
15	T.M.	♀	52	48 hrs. 72 hrs.	- -	Healthy
16	S.Y.	♂	44	48 hrs. 72 hrs.	- -	Healthy
17	S.Y.	♂	35	48 hrs. 72 hrs.	- -	Healthy
18	Y.Y.	♂	36	48 hrs. 72 hrs.	- -	Healthy
19	M.A.	♂	20	48 hrs. 72 hrs.	- -	Healthy
20	K.A.	♂	20	48 hrs. 72 hrs.	- -	Healthy

The result of patch test (2)

No.	Test Person	Sex	Age	Time	Result	Condition of test person
21	F.I.	♀	20	48 hrs. 72 hrs.	- -	Healthy
22	T.I.	♀	20	48 hrs. 72 hrs.	- -	Healthy
23	H.O.	♀	20	48 hrs. 72 hrs.	- -	Healthy
24	R.O.	♀	20	48 hrs. 72 hrs.	- -	Healthy
25	K.K	♀	20	48 hrs. 72 hrs.	- -	Healthy
26	E.K.	♀	20	48 hrs. 72 hrs.	- -	Healthy
27	M.K.	♂	20	48 hrs. 72 hrs.	- -	Healthy
28	H.K.	♂	20	48 hrs. 72 hrs.	- -	Healthy
29	H.K.	♂	20	48 hrs. 72 hrs.	- -	Healthy
30	J.K.	♀	20	48 hrs. 72 hrs.	- -	Healthy
31	Y.S.	♀	20	48 hrs. 72 hrs.	- -	Healthy
32	M.S.	♀	20	48 hrs. 72 hrs.	- -	Healthy
33	T.S.	♀	20	48 hrs. 72 hrs.	- -	Healthy
34	T.S.	♂	20	48 hrs. 72 hrs.	- -	Healthy
35	Y.S.	♂	20	48 hrs. 72 hrs.	- -	Healthy
36	F.S.	♀	20	48 hrs. 72 hrs.	- -	Healthy
37	H.T.	♀	20	48 hrs. 72 hrs.	- -	Healthy
38	N.T.	♀	20	48 hrs. 72 hrs.	- -	Healthy
39	Y.M.	♂	20	48 hrs. 72 hrs.	- -	Healthy
40	S.Y.	♂	20	48 hrs. 72 hrs.	- -	Healthy
41	Y.W.	♀	20	48 hrs. 72 hrs.	- -	Healthy

TRANSLATION

Specialist dermatological assessment of a

PATCH TEST

carried out by

Prof.Dr.med. H. Tronnier
Director of the Dermatological Clinic
of the City Hospital

D-4600 Dortmund, FRG
Beurhausstraße 40
Tel. 02 31/54 22 15 50

Date: Sept. 10, 1985

Substance tested:	Emulsion with 10% Lusantan T3 (new name: Uvinul T 150)
Commercial concentration:	
Test concentration:	in:
Amount applied:	mg test substance/cm ² skin
Manufacturer:	BASF Aktiengesellschaft, D-6700 Ludwigshafen, FRG
Utilization of test substance:	
Test subjects:	50, number with eczema: 7

Principle

The patch test is used to detect a primary skin irritation or a contact allergy by epidermal contact on a limited site over a limited time with the test substance to be investigated.

Method

The substance to be tested is applied to clinically healthy skin and kept in place using a commercial test patch.

The test patch is removed after 24 hours and the test field is assessed. Further assessments are carried out after 48 and 72 hours.

Test field

Dorsum

Test form/Results

Serial No.	Test subject	Age	Sex	Diagnosis	Reaction		
					24 h	48 h	72 h
1	Lettermann, M.	45	m	healthy	0	0	
2	Heinrichs, M.	59	f	healthy	0	0	
3	Heinrichs, E.	67	m	healthy	0	0	
4	Peil, M.	25	m	healthy	0	0	
5	v. Glinski,	48	f	healthy	0	0	
6	Franke, M.	20	m	healthy	0	0	
7	Vieth, R.	19	f	healthy	0	0	
8	Fuhr, H.-D.	57	m	healthy	0	0	
9	Wille, R.M.	43	f	allergy	0	0	
10	Wille, Jan	17	m	healthy	0	0	
11	Wille, K.	19	f	acne	0	0	
12	Wende, D.	17	f	acne	0	0	
13	Wende, H.	74	m	healthy	0	0	
14	Wende, Elis.	70	f	healthy	0	0	
15	Wagemann, W.	39	m	healthy	0	0	
16	Kuhnke, B.	35	f	healthy	0	0	
17	Kuhnke, W.	37	m	healthy	0	0	
18	Hartmann, P.	30	f	healthy	0	0	
19	Hartmann, R.	34	m	healthy	0	0	
20	Fischer, K.W.	40	m	healthy	0	0	
21	Rattay, I.	50	f	healthy	0	0	
22	Eveleyn Muj.	36	f	healthy	0	0	
23	Wölcke, U.	47	m	pollin.	0	0	
24	Overbeck, E.	55	f	allergy	0	0	
25	Neuberg, Ch.	64	f	allergy	0	0	

Test form/Results

Serial No.	Test subject	Age	Sex	Diagnosis	Reaction		
					24 h	48 h	72 h
26	Kruscha, V.	27	f	healthy	0	0	
27	Fischer, A.	34	f	healthy	0	0	
28	Schmiedl, S.	19	f	healthy	0	0	
29	Holtmann, Kai	18	m	healthy	0	0	
30	Meier, I.	16	m	healthy	0	0	
31	Sladek, St.	26	f	acne	0	0	
32	Maschmann, E.	38	f	healthy	0	0	
33	Pfingsten, S.	18	f	healthy	0	0	
34	Braun, St.	17	m	healthy	0	0	
35	Kühn, W.	40	m	healthy	0	0	
36	Neuberg, B.	35	f	diab.	0	0	
37	Henseler, W.	46	f	healthy	0	0	
38	Wölcke, M.	40	f	vittiligo	0	0	
39	Goldscheid, E.	38	f	psoriasis	0	0	
40	Beckmann, O.	45	m	healthy	0	0	
41	Lettermann, U.	32	f	healthy	0	0	
42	Wende, D.	37	f	allergy	0	0	
43	Wagemann, A.	30	f	allergy	0	0	
44	Fischer, E.	38	f	diab.	0	0	
45	Trottenberg	63	f	varices	0	0	
46	Steinert, H.	45	f	healthy	0	0	
47	Zeis, Renate	45	f	healthy	0	0	
48	Wrede, R.M.	18	m	allergy	0	0	
49	Suella, I.	18	f	allergy	0	0	
50	Gehrke, I.	30	f	healthy	0	0	

Evaluation

Ø	no irritation
±	slight or doubtful erythema
+	marked erythema (including urticarial)
++	severe erythema and/or papulation
+++	dense papules and/or vesicles
++++	vesiculation or necrosis

Assessment of the results and conclusions having regard to the envisaged use of the product:

No positive or doubtful reaction to the test product was found after 24 and 48 hours; thus, this test provides no indication of a primary irritating effect or challenge of an allergic reaction.

Signed:
Prof.Dr. H. Tronnier
(Name of the testing physician)

N. Nübler, Oct 15, 1970
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Dipl.-Übers. U. NÜBLER
(Responsible for correct translation)